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**RECEIVED**  
**CENTRAL FAX CENTER**  
**JAN 03 2006**

**To:** Examiner: Vanel Frenel **From:** Alexander J. Burke  
**Fax:** 571-273-8300 **Pages:** 48  
**Phone:** 571-272-6769 **Date:** January 3, 2006  
**Re:** Application of: Klaus Abraham-Fuchs  
Serial No. 09/742,268  
Art Unit: 3626

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Attached is the following: Fee Transmittal 1 pp; Appeal Brief 46 pp

For Application No.: 09/742,268  
Filing Date: December 20, 2000  
First Named Inventor: Klaus Abraham-Fuchs  
Group Art Unit: 3626  
Attorney Docket: 1999P03882US

**CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8**

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*Alexander J. Burke*  
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*3 January 2006*  
Date

PTO/SB/17 (12-04v2)

Approved for use through 07/31/2006. OMB 0651-0032

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Effective on 12/08/2004. Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4018). <b>FEE TRANSMITTAL</b> <b>For FY 2005</b>		<b>Complete if Known</b> Application Number <b>09/742,288</b> <b>RECEIVED</b> Filing Date <b>December 20, 2000</b> <b>CENTRAL FAX CENTER</b> First Named Inventor <b>Klaus Abraham-Fuchs</b> <b>JAN 03 2006</b> Examiner Name <b>Vanel Frenel</b> Art Unit <b>3626</b> Attorney Docket No. <b>1999P03882US</b>	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27			
TOTAL AMOUNT OF PAYMENT	(\$)	500.00	

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## FEE CALCULATION

## 1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

## 2. EXCESS CLAIM FEES

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180
<b>Total Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>
- 20 or HP = _____ x _____ = _____		
HP = highest number of total claims paid for, if greater than 20.		
<b>Indep. Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>
- 3 or HP = _____ x _____ = _____		
HP = highest number of independent claims paid for, if greater than 3.		

## 3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
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## 4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

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SUBMITTED BY		Registration No.	Telephone
Signature	<i>Alexander J. Burke</i>	(Attorney/Agent) 40,425	732-321-3023
Name (Print/Type)	Alexander J. Burke	Date	January 3, 2006

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
Before the Board of Patent Appeals and Interferences

RECEIVED  
CENTRAL FAX CENTER  
JAN 03 2006

Inventor: Klaus Abraham-Fuchs et al.  
Application No.: 09/742,268  
Filed: December 20, 2000  
Title: Method and System for Allowing a Neurologically Diseased  
Patient to Self-Monitor the Patient's Actual State  
Examiner: Vanel Frenel  
Art Unit: 3626

APPEAL BRIEF

May It Please The Honorable Board:

This is Appellants' Brief on Appeal from the final rejection of claims 1 – 28. Please charge the \$500.00 fee for filing this Brief to Deposit Account No. 19-2179. Enclosed is a single copy of this brief.

Please charge any additional fee or credit overpayment to the above-indicated Deposit Account. Enclosed is a single copy of the Brief.

Appellants do not request an oral hearing.

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**I. REAL PARTY IN INTEREST**

The real party in interest of Application Serial No. 09/742,268 is the Assignee of record:

SIEMENS AKTIENGESELLSCHAFT  
WITTELSBACHERPLATZ 2  
80333 MUENCHEN, GERMANY

**II. RELATED APPEALS AND INTERFERENCES**

There are currently no pending appeals and/or interferences related to Application Serial No. 09/742,268

**III. STATUS OF THE CLAIMS**

Claims 1-28 are rejected and the rejection of claims 1-28 are appealed.

**IV. STATUS OF AMENDMENTS**

All amendments were entered and are reflected in the claims included in Appendix I.

**V. SUMMARY OF CLAIMED SUBJECT MATTER**

Independent claim 1 describes a method for allowing a patient, suffering from a neurological disease and receiving medication for the disease, to self-monitor the patient's actual state (page 2, lines 6 – 8). A computer is provided at a location readily accessible to a patient substantially on a daily basis for acquiring information from a patient (page 2, lines 9 – 10). Information is acquired via an interactive procedure from a patient (page 2, lines 8-10). The acquired information is selected from a group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient (page 2, lines 8 – 10). An expert system is provided and is accessible by the computer and the acquired patient information is provided to the expert system for processing (page 2, line lines 10 – 12 and line 18). From the acquired information, at least one quantified indicator that describes the state

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of the patient suffering from a neurological disease which is treated with medication is determined (page 12, lines 17 – 19). The computer is provided with an output device and the quantified indicator is made available to the patient via the output device (page 2, lines 13 – 15).

Claim 2 is dependent on independent claim 1 and includes the limitations contained therein. Claim 2 further includes the feature that the information characterizes a motor function of the patient and the step of acquiring information comprises conducting software-controlled motor function exercises for quantifying at least one of neutral, negative and positive effects of the medication on the patient's state. The negative and positive effects are quantified for processing by the expert system for use in determining the quantified indicator (page 4, line 17 – page 5, line 2).

Claim 3 is dependent on independent claim 1 and includes the limitations contained therein. Claim 3 further includes the feature that the information characterizes a verbal communication ability of the patient, and the step of acquiring information comprises acoustically acquiring speech from the patient and assessing the speech with a speech assessment system having speech recognition algorithms and a phonetic data bank to obtain an information value quantifying at least one of neutral, negative and positive effects of the medication on the speech. The information value is supplied to the expert system for processing by the expert system for use in determining the quantified indicator (page 5, lines 17 – 22).

Claim 4 is dependent on independent claim 1 and includes the limitations contained therein. Claim 4 further includes the feature that the information is information characterizing cognitive abilities of the patient, and the step of acquiring information comprises generating questions requiring a response from the patient to the respective questions. An information value is generated from the responses for quantifying at least one of neutral, negative and positive effects of the medication on the cognitive abilities of the patient. The information value is supplied to the expert system for processing for use in determining the quantified indicator (page lines 9 – 16).

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Claim 8 is dependent on independent claim 1 and includes the limitations contained therein. Claim 8 also includes the feature of obtaining a quantified information value representing the information acquired in the step of acquiring and storing, after each interactive procedure, as stored information with respect to time, at least one of the quantified indicator, the acquired information and the quantified information value (page 7, lines 4 – 11).

Claim 9 is dependent on claim 8 and includes all the limitations of claims 1 and 8. Claim 9 also includes the additional feature of providing the stored information to the expert system for producing an evaluation regarding dosage of the medication based on the stored information and making the evaluation available to the patient at the output device (page 7, lines 12 – 15).

Independent claim 17 describes a system for allowing a patient suffering from a neurological disease and receiving medication for treating the disease, to self-monitor a state of the patient (page 2, lines 6 – 8). A computer readily accessible by the patient is disposed at a location at which the patient is present substantially on a daily basis (page 2, lines 9 – 10). At least one software program installed in the computer is able to execute an interactive procedure with the patient to obtain information selected from the group consisting of information characterizing a motor function of the patient, information characterizing verbal communication abilities of the patient, and information characterizing cognitive abilities of the patient (page 11, lines 5-6 and page 2, lines 8 – 10). An input unit is connected to the computer for use by the patient during the interactive procedure for acquiring the information (page 11, lines 14 – 17). An expert system is accessible by the computer and receives the information and produces a quantified indicator from the information and makes the quantified indicator available to the computer (page 2, lines 10 – 12 and line 18). An output unit is connected to the computer for providing the quantified indicator to the patient (page 2, lines 13 – 15).

Claim 19 is dependent on Independent claim 17 and includes all features contained therein. Claim 19 further includes the feature that the information characterizes verbal communication abilities of the patient and the input unit is an acoustical input unit. The software program assesses speech made by the patient into

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the input unit using speech algorithms and a phonetic data bank and produces a quantified information value representing the verbal communication abilities. The quantified information value is made available to the expert system (page 5, lines 17 – 22).

Claim 21 is dependent on Independent claim 17 and includes all features contained therein. Claim 21 includes the additional feature of a software program for operating the computer to obtain additional information from the patient characterizing a subjective state of health of the patient (page 6, line 18 – page 7, line 3).

Claim 22 is dependent on Independent claim 17 and includes the features contained therein. Claim 22 includes the additional feature wherein the software program in each interactive procedure produces a quantified information value from the information, and further includes a memory accessible by the computer and by the expert system for storing, as stored information relative to time, at least one of the quantified indicator, the information and the quantified information value after each interactive procedure (page 7, lines 4 – 11).

Claim 23 is dependent on claim 22 and includes the features of claims 17 and 22. Claim 23 further includes the feature that the expert system produces an evaluation from the stored information with regard to a dosage of the medication (page 7, lines 12 – 15).

#### **VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

The Examiner has rejected claims 1-18, 20 and 25 as being unpatentable under 35 USC 103(a) over Hennessy et al. (U.S. Patent No. 6,277,071) in view of Correa et al. (U.S. Patent No. 5,882,203) and further in view of Saltzstein et al. (5,941,829).

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The Examiner has rejected claims 19, 21-24 and 26 -28 as being unpatentable under 35 USC 103(a) over Hennessy et al. (U.S. Patent No. 6,277,071) in view of Correa et al. (U.S. Patent No. 5,882,203).

## **VII. ARGUMENT**

Hennessy, et al. when taken alone or in combination with Correa et al. and Saltzstein et al. do not make the present claimed invention unpatentable. Thus, reversal of the Final Rejection (hereinafter termed "rejection") of claims 1-28 under 35 U.S.C. § 103(a) is respectfully requested.

### **Overview of the Cited References**

Hennessy et al. disclose a system for monitoring a chronic disease is disclosed. The monitor includes a database for storing a plurality of patient data entries and sorts the patient data entries according to whether a test threshold is crossed. Each of the patient data entries includes personal information of a patient and a set of guidelines concerning the patient's care. The guideline represents a plurality of rules concerning a patient's care derived from accepted tests used to monitor the disease represented in an algorithm. A processor separates the patient entries designated by the user according to the test thresholds, such as for HbA1c, lipids, liver enzyme and microalbumin, for the disease of diabetes. If the test threshold value derived from the guideline is crossed, an alert sequence is activated, in which the patient is categorized as a high risk patient, the physician is notified, the patient is notified, the health care provider is notified, and the patient's treatment plan is altered to treat the high risk patient (see Hennessy et al.; Abstract).



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Correa et al. discloses a method of detecting depression and its severity. A series of statements formulated to detect the presence and severity of depression are presented to the subject in a multiple item visual analog format. The subject's answers are given a numerical value. The total score is then normatively ranked to determine the presence and severity of the depression. (See Correa et al.; Abstract)

Saltzstein et al discloses a method and apparatus for voice interaction between the service provider to the patient whose life signs, e.g. an electrocardiograph (ECG), concurrently are being monitored are described. Patient data, and preferably patient waveform data, and voice communication are conveyed in real-time on a single, or common, public switched telephone (PSTN) line. A life signs monitor at the patient site is connected to the patient and to a digital simultaneous voice and data (DSVD) device having the ability to digitize and compress the patient's voice and having the ability to decompress and analogize the physician's voice via a standard telephone. A modem modulates and demodulates transmitted and received data over the telephone line. At a remote monitoring site a second modem receives and transmits data over the same telephone line. The second modem is connected with a second DSVD device connected to a display- or printer-equipped receiving station for presentation in textual or graphic form to a remote service provider the patient data, e.g. in the form of an ECG trace. Thus, the service provider has the ability to overview patient life signs monitoring while in real-time, synchronized vocal communication with the patient, and therefore is able to correlate the patient's mental, physical and emotional state with the data being received, as well as for instructing the patient or otherwise reassuring the patient of the proper use of the life signs monitor or diagnosing or prescribing in real-time a response to what is gleaned from the monitoring. (See Saltzstein et al.; Abstract)

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**Rejection of Claims 1-18, 20 and 25 under 35 USC 103(a) over**  
**Hennessy et al. (U.S. Patent No. 6,277,071) in view of Correa et al. (U.S. Patent No.**  
**5,882,203) and further in view of Saltzstein et al. (5,941,829)**

Reversal of the rejection of claims 1 – 18, 20 and 25 under 35 U.S.C. 103(a) as being unpatentable over Hennessy in view of Correa and further in view of Saltzstein is respectfully requested. The rejection erroneously states that claims 1 – 18, 20 and 25 are unpatentable over Hennessy in view of Correa and further in view of Saltzstein for the reasons discussed herein below.

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the examiner to establish a factual basis to support the legal conclusion of obviousness. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596, 1598 (Fed.Cir. 1988). In so doing, the Examiner is expected to make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (CCPA 1966), and to provide a reason why one having ordinary skill in the pertinent art would have been led to modify the prior art or to combine prior art references to arrive at the claimed invention. Such reason must stem from some teaching, suggestion, or implication in the prior art as a whole or knowledge generally available to one having ordinary skill in the art. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed.Cir. 1988), *cert. denied*, 488 U.S. 825 (1988); *Ashland Oil Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 28, 293, 227 USPQ 657, 664 (Fed.Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986); *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed.Cir. 1984). These showings by the Examiner are an essential part of complying with the burden of presenting a *prima facie*

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case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed.Cir. 1992).

CLAIMS 1, 6, 7 and 10 - 16

The present claimed invention describes a method for allowing a patient, suffering from a neurological disease and receiving medicine for that disease, to self monitor his actual state. Hennessy, Correa and Saltzstein neither disclose nor suggest the claimed method for the following reasons.

Hennessy et al. disclose a system for monitoring a chronic disease. The system stores patient data entries and sorts the data according to whether a test threshold has been crossed. When the threshold is crossed, the physician is notified, the patient is notified, the health care provider is notified, and the patient's treatment plan is altered. Hennessy et al. (with Correa and/or Saltzstein) neither disclose nor suggest "a method for allowing a patient, suffering from a neurological disease and receiving medication for said disease to self-monitor the patient's actual state." Contrary to the assertions made in the Office Action, in Col 1, lines 50-67 to Col 2, line 35 Hennessy et al. actually disclose blood tests and examinations associated with treating a patient suffering from diabetes. Diabetes is not a neurological disease nor are the blood tests associated with diabetes used to ascertain "motor function of the patient...verbal communication ability of the patient...and cognitive abilities of the patient" as in the present claimed invention.

The applicant also respectfully disagrees with the assertion made in the Office Action that Hennessy disclose the step of "providing a computer at a location readily accessible to a patient substantially on a daily basis." While Hennessy does disclose in Col 2, lines 8-67 "the data may then be downloaded and/or transferred to a computer," the

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computer is not a requirement. Additionally, in Col 5, lines 30-67 Hennessy disclose a central database and computer memory. However, Hennessy (with Correa and/or Saltzstein) neither disclose nor suggest "providing a computer at a location readily accessible to a patient substantially on a daily basis," as in the present claimed invention.

The applicant further respectfully disagrees with the assertion that Hennessy disclose "conducting an interactive procedure between said patient and said computer to acquire information in said computer from the group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient." Rather, in Col 6, lines 30-67 to Col 7, line 26 Hennessy disclose what information is included in the patient record such as test data, which includes "the office date, practitioner, and office visit comments. Clinical information, i.e. weight, height, blood pressure, smoking status, blood glucose recordations, neuropathy, skin condition, eye exam, are stored." Also, quality of life indicators, a quality plan, medication, therapies and treatments are also included in the patient record disclosed by Hennessy. The information acquired by Hennessy is general information about the physiology of the patient. This is unlike the present claimed invention which discloses an interactive procedure between a patient and a computer used "to acquire information in said computer from the group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient" as in the present claimed invention. In fact, the information acquired by Hennessy would not be "the acquired information" of the present invention due to the distinct difference in the information acquired. Specifically, the information in Hennessy is not "selected from the group consisting of information characterizing a motor function of the patient, information characterizing a verbal

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communication ability of the patient, and information characterizing cognitive abilities of the patient” as in the present claimed invention. Furthermore, Hennessey is directed towards monitoring a physiological disease i.e. diabetes, which is not “a neurological disease” as in the present claimed invention and Hennessey (with the other cited references) provides no 35 USC 112 compliant enabling disclosure of the claimed arrangement.

Correa disclose a method of detecting depression and its severity. Correa, similarly to Hennessey, neither disclose nor suggest “making an expert system accessible by said computer and supplying said information from said computer to said expert system and, in said expert system, determining at least one quantified indicator describing the state of the patient suffering from a neurological disease, which is treated by medication” as in the present claimed invention. Nor does Correa (with Hennessey and/or Saltzstein) disclose “providing said computer with an output device and making said quantified indicator available to the patient via said output device” as stated in the Office Action and claimed in the present invention. Contrary to the assertions made in the Office Action, in Col 1, lines 4-67 to Col 2, line 67 and Col 3, lines 1-41, Correa actually disclose a method “for detecting the presence and severity of depression by means of measuring the subject’s color perception, and changes in color perception.” Correa repeatedly recite throughout the application that color directly correlates to a level of depression and Correa specifically requires color to be obtained as an indication of the level of depression of the patient. Correa (with Hennessey and/or Saltzstein) neither disclose nor suggest providing information characterizing a verbal communication ability, motor function, or cognitive ability of a patient to “an expert system for processing thereby, and determining...at least one quantified indicator describing the state of the patient suffering form a neurological disease which is treated with medication,” as in the present claimed invention.

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On page 2 of the Final Rejection, the Examiner acknowledges that neither Hennessy nor Correa disclose the present invention as claimed in Claim 1. However, the Examiner further cites Saltzstein as disclosing the claimed features. Applicant respectfully disagrees. Specifically, the system disclosed by Saltzstein is wholly unlike the present claimed invention. The Saltzstein system "relates to remote medical patient monitoring. More particularly, it involves real-time communication of patient data, especially waveform data, over a single telephone line concurrently with both medical practitioner and patient voice" (see Saltzstein, col. 1, lines 14 – 18). Saltzstein is merely concerned with concurrent transmission of voice and waveform data between patient and practitioner and this system requires simultaneous interaction between a patient **AND** a medical practitioner. The Saltzstein system is **NOT** a "method for allowing a patient...to self-monitor the patient's actual state" as described in the present claimed invention. This distinction is further clarified on page 4, lines 11 – 16 of the present specification which states that the "inventive method enable the patient to simply receive items of information about his or her actual state, so that the patient can gain knowledge about his or her state or state of health at arbitrarily short time...intervals. Otherwise, a visit to the doctor would be necessary...Moreover, a physician need not be consulted when the examination results indicates an improvement of the state, or stability". Thus, the present claimed invention is wholly unlike the system disclosed by Saltzstein which requires interaction with a medical practitioner. Therefore, Saltzstein is **not** a "self-monitoring" system as in the present claimed invention.

Applicant respectfully submits that the Examiner misinterprets and fundamentally misunderstands the system disclosed by Saltzstein. The cited portion of Saltzstein (col. 8, lines 19 – 67 and col. 9, line 10) is erroneously equated with the present claimed invention and with the other cited references provides no 35 USC 112 compliant enabling disclosure

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of the claimed arrangement. Rather, the cited section of Saltzstein merely discloses various forms of a “digital simultaneous voice and data device (DSVD)” wherein the DSVD is able to simultaneously transmit voice and other data obtained from a life signs monitor **between a patient and a practitioner**. Saltzstein states that the DSVD controls the signal processing and the transmission of data therebetween. Thus, Saltzstein discloses a system for aiding a physician in diagnosing and handling a patient by being able to verbally communicate with the patient while receiving data representing vital signs of the patient. Therefore, Saltzstein is not a “self-monitoring system” as in the present claimed invention.

Furthermore, similarly to both Hennessy and Correa, Saltzstein is provides no 35 USC 112 compliant enabling disclosure that the information is acquired “via an interactive procedure” and “is selected from a group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient” as in the present claimed invention. Specifically, in column 6, lines 11 – 27, Saltzstein defines “life signs monitor 16” that is able to acquire information from the patient connected thereto. The information acquired by these devices is **NOT** equivalent the “acquired information” of the present claimed invention. Further, Saltzstein neither discloses nor suggests that the “life signs monitor” acquires information “via an interactive procedure” as in the present claimed invention.

In fact, Saltzstein provides a system that is in direct contrast with the method of the present claimed invention. The only feature of Saltzstein that is “interactive” is the conversation between the patient and the practitioner which “assists the physician in interpreting monitored vital signs [and]...tends to place the patient at greater ease” to reduce stress associated with monitoring (see Saltzstein, col. 8, lines 64 – 67). This is

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wholly unlike the present claimed invention which "provides a computer...for acquiring patient information...providing an expert system accessibly by the computer [and] providing said acquired patient information to said expert system". Contrary to the present invention, Saltzstein acquires information via a monitoring device and provides the information to a physician while simultaneously supporting communication between the patient and the practitioner.

Additionally, while verbal communication between patient and practitioner occurs, this is not equivalent to "information characterizing a verbal communication ability of the patient" as in the present claimed invention. Saltzstein provides no means for evaluating the verbal communication aside from the practitioner listening thereto and provides no "expert system" for "determining from the acquired information, at least one quantified indicator describing the state of the patient" as in the present claimed invention. Saltzstein further describes the importance of having this information evaluated by another person because the practitioner is better able to correlate this information with the vital statistics when interpreting this data. Therefore, Saltzstein teaches away from the present claimed method and is wholly unrelated thereto. Saltzstein relies on the input of a medical practitioner and therefore is not a "self-monitoring" system as in the present claimed invention.

It is also respectfully submitted that there is no reason or motivation to combine these references. Hennessy is directed towards monitoring a chronic disease through physiological indicators while Correa are concerned with measuring the severity of depression through color perception. Saltzstein is merely concerned with supporting simultaneous voice and data communication between a patient and a practitioner. The type of disease monitored and means for monitoring this disease in each of Hennessey et al. and



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Correa are totally unrelated. Individual diseases each require unique and subjective methods of monitoring and treatment. Thus, there would be no reason or motivation to combine teachings on treating and monitoring two different and unrelated diseases to produce a method or system for self-monitoring a third unrelated disease, a neurological disease, as in the present claimed invention. Additionally, the Examiner cites column 2, lines 7 – 11 of Saltzstein as providing motivation to combine Saltzstein with each of Correa and Hennessy. However, Applicant respectfully disagrees. Synchronizing voice and data for a physician to correlate bodily activities, mental state and physical condition is not motivation to combine with Hennessy and Correa to produce a “method for allowing a patient, suffering from a neurological disease...to self-monitor the patient’s actual state” as in the present claimed invention. Since Saltzstein requires interaction between a patient and another human being, there is no reason to use the teachings of Saltzstein to create a “self-monitoring system” wherein an “expert system” determines “from the acquired information, at least one quantified indicator describing the state of the patient suffering from a neurological disease which is treated with medication” as in the present claimed invention.

Additionally, even if there is some motivation to combine these references, such a combination would produce a system that monitors chronic disease and depression through physiological indicators and color perception whereby a patient suffering could simultaneously communicate with a practitioner while data is transferred therebetween. This combination would still not disclose “a method for allowing a patient, suffering from a neurological disease and receiving medication for said disease to self-monitor the patient’s actual state” as in the present claimed invention. Nor would such a combination disclose “providing a computer at a location readily accessible to a patient substantially on a daily basis” as in the present claimed invention. This combination would also not disclose

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“conducting an interactive procedure between said patient and said computer to acquire information in said computer from the group consisting of **information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient**” as in the present claimed invention. Nor would the combination disclose both “making an expert system accessible by said computer and supplying said information from said computer to said expert system and, in said expert system, determining at least one quantified indicator describing the state of the patient suffering from a neurological disease, which is treated by medication” and “providing said computer with an output device and making said quantified indicator available to the patient via said output device” as in the present claimed invention.

Claims 6, 7 and 10 – 16 are dependent on independent claim 1 and are considered patentable for the reasons present above with respect to claim 1. Consequently, it is respectfully submitted that the rejection of claims 1, 6, 7 and 10 – 16 be withdrawn.

#### CLAIMS 2 - 4

Claims 2 – 4 are dependent on Independent claim 1 and are considered patentable for the reasons presented above. Claims 2 – 4 are also considered patentable because Correa (with Hennessy and/or Saltzstein) provide no 35 USC 112 compliant enabling disclosure of the featured claimed in claims 2 – 4 of the present invention. The applicant also respectfully disagrees with the assertion in the Office Action that Correa, Hennessy and Saltzstein (alone or in combination) disclose “information characterizing a motor function of said patient,” or “information characterizing a verbal communication ability of said patient,” or “information characterizing cognitive abilities of the patient” as in the present claimed invention. Correa et al. is concerned with information regarding depression

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in a patient. This is unlike the present claimed invention which concerns motor function, verbal communication ability, and cognitive ability. Additionally, contrary to the assertion regarding Claim 2, Col. 1, lines 66-67 and Col 2, line 67 and Col 3, lines 1-41, of Correa et al. disclose including questions "negatively and positively phrased avoid acquiescence bias." This is not the same as determining whether a medication is working by looking for negative or positive effects of the medication on the state of the patient. Nor does Correa, Hennessy and Saltzstein disclose or suggest "quantifying said negative and positive effects for processing by said expert system for use in determining said quantified indicator" as claimed in claims 2 - 4 of the present invention.

The Examiner erroneously cites column 8, lines 51 - 67 of Saltzstein as "quantifying neutral...effects of said medication". Applicant respectfully disagrees. Rather, the cited section of Saltzstein discloses promoting better voice communication between patient and physician so that the physician could inquire past the information received from the monitors to better interpret the data and to potentially alleviate any stress. This is not the method as claimed in claims 2 - 4 which discloses that quantified positive and negative effects are used by "said expert system for use in determining said quantified indicator". Saltzstein disclose interpretation by a human counterpart which is wholly unlike the present claimed invention. Combining the system of Saltzstein with the system of both Hennessy and Correa provides no 35 USC 112 compliant enabling disclosure that makes the present invention as claimed in claims 2 - 4 unpatentable. Consequently, it is respectfully submitted that the rejection of claims 2 - 4 be withdrawn.

#### CLAIM 5

Claim 5 is dependent on Independent claim 1 and is considered patentable for the reasons presented above regarding claim 1. Claim 5 is also considered patentable for the

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following reasons. Applicant disagrees with the contention that Hennessy et al. disclose “a method comprising the step of acoustically entering said responses from said patient into said computer” as in claim 5 of the present claimed invention in Col 6., lines 12-67. Hennessy et al. actually disclose in this passage that the information is included in the patient record. Hennessy et al. (with Correa et al.) neither disclose nor suggest “a method comprising the step of acoustically entering said responses from said patient into said computer” as claimed in claim 5 of the present invention.

#### CLAIM 8

Claim 8 is dependent on Independent claim 1 and is considered patentable for the reasons presented above with respect to claim 1. Claim 8 is also considered patentable because Hennessy (with Correa and/or Saltzstein) provide no 35 USC 112 compliant enabling disclosure that makes the present invention as claimed in claim 8 unpatentable. Specifically, as acknowledged by the Examiner, Hennessy neither discloses nor suggests “acquiring information via an interactive procedure” as in the present claimed invention. Additionally, as discussed above with respect to claim 1, Hennessy neither discloses nor suggests that “the acquired information is selected from a group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient” as in the present claimed invention.

Additionally, the Examiner cites column 7, line 14 – column 8, line 67 as disclosing the claimed feature. Applicant respectfully disagrees. Rather, in the section cited by the Examiner, Hennessy discloses a plurality of windows containing patient data that include many pertinent patient-related and practitioner related information. This information is used to generate a guideline for a treatment plan for a population of diabetic patients. The

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guideline includes a plurality of tests, schedules for the plurality of tests to be performed and threshold values which, if exceeded, would generate alerts. The user of the system is able to modify the guideline in order to stray from a default depending on the patient population. Hennessy (with the other cited references) provides that the values changed from the default values are to be stored. However, this is wholly unlike the present claimed invention. Hennessy neither discloses nor suggest "obtaining a quantified information value representing said information acquired" in the interactive procedure as in the present claimed invention. Instead, Hennessy requires information to be input by a user and not "acquired via an interactive procedure" as in the present claimed invention. Furthermore, Hennessy neither discloses nor suggests "storing, after each interactive procedure, as stored information with respect to time, at least one of said quantified indicator, said acquired information and said quantified information value" as in the present claimed invention. Consequently, it is respectfully requested that the rejection of claim 8 be withdrawn.

#### CLAIM 9

Claim 9 is dependent on Independent claim 8 and is considered patentable for the reasons presented above with respect to claims 1 and 8. Claim 9 is also considered patentable because Hennessy (with Correa and/or Saltzstein) provide no 35 USC 112 compliant enabling disclosure that makes the present invention as claimed in claim 9 unpatentable. Specifically, as acknowledged by the Examiner, Hennessy neither discloses nor suggests "acquiring information via an interactive procedure" as in the present claimed invention. Additionally, as discussed above with respect to claim 1, Hennessy neither discloses nor suggests that "the acquired information is selected from a group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient" as in the present claimed invention.

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Applicant respectfully submits that the Examiner fundamentally misinterprets and misunderstands the system as disclosed by Hennessy. Column 6, lines 52 – 67 and column 7, lines 1 – 67 are cited as disclosing the present invention as claimed in claim 9. Applicant respectfully disagrees. Rather, similarly as discussed above with respect to the rejection of claim 8, Hennessy merely discloses the generation of a quality plan for treatment of a patient population having diabetes. The patient record of Hennessy includes the quality plan that is generated from a selected treatment guideline. All of the information that makes up each of the patient record and the guideline are input by a user and NOT by “acquiring information, via an interactive procedure, from a patient” as in the present claimed invention. Further, Hennessy neither discloses nor suggest “producing an evaluation regarding dosage of said medication based on said stored information” as in the present claimed invention. Moreover, the information used by Hennessy to generate the quality plan and guideline is wholly unlike the “acquired information” of the present claimed invention which “is selected from a group consisting of information characterizing motor function of the patient, information characterizing verbal communication ability of the patient, and information characterizing cognitive abilities of the patient”. Therefore, Hennessy neither discloses nor suggests “providing said stored information to said expert system for producing an evaluation regarding dosage of said medication based on said stored information” as in the present claimed invention. Consequently, it is respectfully submitted that the rejection of claim 9 be withdrawn.

CLAIMS 17, 18, 20 and 25

Applicant notes that there is no affirmative rejection made in the Final Office Action over claim 17 but assumes that claim 17 is rejected on similar basis as claim 1 and

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is treated as such herein. The present claimed invention describes a system for allowing a patient, suffering from a neurological disease and receiving medicine for that disease, to self monitor his actual state. Hennessy, Correa and Saltzstein neither disclose nor suggest the claimed system for the following reasons.

Hennessy disclose a system for monitoring a chronic disease. The system stores patient data entries and sorts the data according to whether a test threshold has been crossed. When the threshold is crossed, the physician is notified, the patient is notified, the health care provider is notified, and the patient's treatment plan is altered. Hennessy (with Correa and/or Saltzstein) neither disclose nor suggest "a system for allowing a patient, suffering from a neurological disease and receiving medication for treating said disease to self-monitor a state of the patient" as in the present claimed invention. Contrary to the assertions made in the Office Action, in Col 1, lines 50-67 to Col 2, line 35 Hennessy actually discloses blood tests and examinations associated with treating a patient suffering from diabetes. Diabetes is not a neurological disease nor are the blood tests associated with diabetes used to ascertain "motor function of the patient...verbal communication ability of the patient...and cognitive abilities of the patient" as in the present claimed invention.

The applicant also respectfully disagrees with the assertion made in the Office Action that Hennessy discloses "a computer readily accessible by the patient disposed at a location at which said patient is present substantially on a daily basis" as in the present claimed invention. While Hennessy does disclose in Col 2, lines 8-67 "the data may then be downloaded and/or transferred to a computer," the computer is not a requirement. Additionally, in Col 5, lines 30-67, Hennessy disclose a central database and computer memory. However, Hennessy (with Correa and/or Saltzstein) neither disclose nor suggest

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“a computer readily accessible to a patient,...substantially on a daily basis,” as in the present claimed invention.

The applicant further respectfully disagrees with the assertion that Hennessy disclose “an interactive procedure with said patient to obtain information selected from the group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient” as in the present claimed invention. Rather, in Col 6, lines 30-67 to Col 7, line 26 Hennessy discloses what information is included in the patient record such as test data, which includes “the office date, practitioner, and office visit comments. Clinical information, i.e. weight, height, blood pressure, smoking status, blood glucose recordations, neuropathy, skin condition, eye exam, are stored.” Also, quality of life indicators, a quality plan, medication, therapies and treatments are also included in the patient record disclosed by Hennessy. Thus, the information acquired by Hennessy is general information about the physiology of the patient. This is unlike the present claimed invention which discloses an interactive procedure between a patient and a computer used “to obtain information selected from the group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient” as in the present claimed invention. In fact, the information acquired by Hennessy would not be “the acquired information” of the present invention due to the distinct difference in the information acquired. Specifically, the information in Hennessy is not “selected from the group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient” as in the present claimed invention. Furthermore,



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Hennessey is directed towards monitoring a physiological disease i.e. diabetes, which is not "a neurological disease" as in the present claimed invention.

Correa disclose a method of detecting depression and its severity. Similarly to Hennessey, Correa neither disclose nor suggest "an expert system accessible by said computer able to receive said information and produce a quantified indicator from said information and making said quantified indicator available to said computer" as in the present claimed invention. Nor does Correa (with Hennessey and/or Saltzstein) disclose "an output unit connected to said computer for providing said quantified indicator to the patient" as asserted in the Office Action and claimed in the present invention. Contrary to the assertions made in the Office Action, in Col 1, lines 4-67 to Col 2, line 67 and Col 3, lines 1-41, Correa actually discloses a method "for detecting the presence and severity of depression by means of measuring the subject's color perception, and changes in color perception." Correa repeatedly recites throughout the application that color directly correlates to a level of depression and Correa specifically requires color to be obtained as an indication of the level of depression of the patient. Correa (with Hennessey and/or Saltzstein) neither discloses nor suggests providing information characterizing a verbal communication ability, motor function, or cognitive ability of a patient to "an expert system...able to receive said information and produce a quantified indicator from said information" that describes the state of the patient suffering from a neurological disease as in the present claimed invention.

On page 2 of the Final Rejection, the Examiner acknowledges that neither Hennessey nor Correa disclose the present invention as claimed in Claim 1. However, the Examiner further cites Saltzstein as disclosing the claimed features. Applicant respectfully disagrees. Specifically, the system disclosed by Saltzstein is wholly unlike the present claimed

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invention. The Saltzstein system “relates to remote medical patient monitoring. More particularly, it involves real-time communication of patient data, especially waveform data, over a single telephone line concurrently with both medical practitioner and patient voice” (see Saltzstein, col. 1, lines 14 – 18). Saltzstein is merely concerned with concurrent transmission of voice and waveform data between patient and practitioner and involves simultaneous interaction between a patient AND a medical practitioner as discussed later. The Saltzstein system is NOT a “system for allowing a patient...to self-monitor the patient’s actual state” as described in the present claimed invention. This distinction is further clarified on page 4, lines 11 – 16 of the present specification which states that the “inventive method enable the patient to simply receive items of information about his or her actual state, so that the patient can gain knowledge about his or her state or state of health at arbitrarily short time...intervals. Otherwise, a visit to the doctor would be necessary...Moreover, a physician need not be consulted when the examination results indicates an improvement of the state, or stability”. Thus, the present claimed invention is wholly unlike the system disclosed by Saltzstein which requires interaction with a medical practitioner. Therefore, Saltzstein is not a “self-monitoring” system as in the present claimed invention.

Applicant respectfully submits that the Office Action misinterprets and fundamentally misunderstands the system disclosed by Saltzstein. The cited portion of Saltzstein (col. 8, lines 19 – 67 and col. 9, line 10.) which is erroneously equated with the present claimed invention provides no 35 USC 112 compliant enabling disclosure thereof. Rather, the cited section of Saltzstein merely discloses various forms of a “digital simultaneous voice and data device (DSVD)” wherein the DSVD is able to simultaneously transmit voice and other data obtained from a life signs monitor between a patient and a practitioner. Saltzstein states that the DSVD controls the signal processing and the

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transmission of data therebetween. Thus, Saltzstein discloses a system for aiding a physician in diagnosing and handling a patient by being able to verbally communicate with the patient while receiving data representing vital signs. Therefore, Saltzstein is not a "self-monitoring system" as in the present claimed invention.

Furthermore, similarly to both Hennessy and Correa, Saltzstein is provides no 35 USC 112 compliant enabling disclosure that the information acquired "via an interactive procedure...is selected from a group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient" as in the present claimed invention. Specifically, in column 6, lines 11 – 27, Saltzstein defines "life signs monitor 16" that is able to acquire information from the patient connected thereto. The information acquired by these devices is NOT equivalent the "obtained information" of the present claimed invention. Further, no where in Saltzstein does it state that the "life signs monitor" acquires information via "an interactive procedure" as in the present claimed invention.

In fact, the teaching of the Saltzstein system is in direct contrast with the present claimed invention. The only feature of Saltzstein that is "interactive" is the conversation between the patient and the practitioner which "assists the physician in interpreting monitored vital signs [and]...tends to place the patient at greater ease" to reduce stress associated with monitoring (see Saltzstein, col. 8, lines 64 – 67). This is wholly unlike the present claimed invention which "provides a computer...for acquiring patient information...providing an expert system accessibly by the computer [and] providing said acquired patient information to said expert system". Contrary to the present invention, Saltzstein acquires information via a monitoring device and provide the information to a

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physician while simultaneously supporting communication between the patient and the practitioner.

Additionally, while verbal communication between patient and practitioner occurs, this is not equivalent to "information characterizing a verbal communication ability of the patient" as in the present claimed invention. Saltzstein provides no means for evaluating the verbal communication aside from the practitioner listening thereto. There is no mention of an "expert system" for "determining from the acquired information, at least one quantified indicator describing the state of the patient" as in the present claimed invention. Saltzstein further describes the importance of having this information evaluated by another person because the practitioner is better able to correlate this information with the vital statistics when interpreting this data. Therefore, Saltzstein teaches away from the present claimed method and is wholly unrelated thereto. Saltzstein relies on the input of a medical practitioner and therefore is not a "self-monitoring" system as in the present claimed invention.

It is also respectfully submitted that there is no reason or motivation to combine these references. Hennessy et al. is directed towards monitoring a chronic disease through physiological indicators while Correa et al. are concerned with measuring the severity of depression through color perception. Saltzstein is merely concerned with supporting simultaneous voice and data communication between a patient and a practitioner. The type of disease monitored and means for monitoring this disease in each of Hennessey et al. and Correa et al. are totally unrelated. Individual diseases each require unique and subjective methods of monitoring and treatment. Thus, there would be no reason or motivation to combine teachings on treating and monitoring two different and unrelated diseases to produce a method or system for self-monitoring a third unrelated disease, a neurological

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disease, as in the present claimed invention. Additionally, the Examiner cites column 2, lines 7 – 11 of Saltzstein as providing motivation to combine Saltzstein with each of Correa and Hennessy. However, Applicant respectfully disagrees. Synchronizing voice and data for a physician to correlate bodily activities, mental state and physical condition is not motivation to combine with Hennessy and Correa to produce a “method for allowing a patient, suffering from a neurological disease...to self-monitor the patient’s actual state” as in the present claimed invention. Since Saltzstein requires interaction between a patient and another human being, there is no reason to use the teachings of Saltzstein to create a “self-monitoring system” wherein an “expert system” determines “from the acquired information, at least one quantified indicator describing the stat of the patient suffering from a neurological disease which is treated with medication” as in the present claimed invention.

Additionally, even if there is some motivation to combine these references, such a combination would produce a system that monitors chronic disease and depression through physiological indicators and color perception whereby a patient suffering could simultaneously communicate with a practitioner while data is transferred therebetween. This combination would still not disclose “a method for allowing a patient, suffering from a neurological disease and receiving medication for said disease to self-monitor the patient’s actual state” as in the present claimed invention. Nor would such a combination disclose “providing a computer at a location readily accessible to a patient substantially on a daily basis” as in the present claimed invention. This combination would also not disclose “at least one software program installed in said computer able to execute an interactive procedure with said patient to obtain information selected from the group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information

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**characterizing cognitive abilities of the patient” as in the present claimed invention. Nor would the combination disclose both “an expert system accessible by said computer able to receive said information and produce a quantified indicator from said information and making said quantified indicator available to said computer” and “an output unit connected to said computer for providing said quantified indicator to the patient” as in the present claimed invention.**

**Claim 25 is dependent on independent claim 17 and is considered patentable for the same reasons as discussed above with respect to claim 17. Consequently, it is respectfully submitted that the rejection of claims 17 and 25 be withdrawn.**

**In view of the above remarks, it is respectfully submitted that Hennessy et al., Correa et al. and Saltzstein et al, when taken alone or in combination provide no 35 USC 112 compliant enabling disclosure showing the features claimed in claim 1 and 17. As claims 2-16 are dependent on claim 1 and claims 18, 20 and 25 are dependent on claim 17, it is respectfully submitted that claims 2-16 and 18, 20 and 25 are patentable for the same reasons as claim 1 and 17 discussed above. It is thus further respectfully submitted that this rejection is satisfied and should be withdrawn.**

**Rejection of Claims 19, 21 - 24 and 26 - 28 under 35 USC 103(a) over**

**Hennessy et al. (U.S. Patent No. 6,277,071)**

**in view of Correa et al. (U.S. Patent No. 5,882,203)**

**Reversal of the rejection of claims 19, 21 - 24 and 26 - 28 under 35 U.S.C. 103(a) as being unpatentable over Hennessy in view of Correa is respectfully requested. The rejection erroneously states that claims 19, 21 - 24 and 26 - 28 are unpatentable over Hennessy in view of Correa for the reasons discussed herein below.**

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CLAIMS 19, 21, 27 and 28

Claims 19, 21, 27 and 28 are dependent on independent claim 17 and are considered patentable for the reasons discussed above with respect to claim 17. Specifically, Hennessy discloses a system for monitoring a chronic disease. The system stores patient data entries and sorts the data according to whether a test threshold has been crossed. When the threshold is crossed, the physician is notified, the patient is notified, the health care provider is notified, and the patient's treatment plan is altered. Hennessy (with Correa) neither disclose nor suggest "a system for allowing a patient, suffering from a neurological disease and receiving medication for treating said disease to self-monitor a state of the patient" as in the present claimed invention. Contrary to the assertions made in the Office Action, in Col 1, lines 50-67 to Col 2, line 35 Hennessy actually disclose blood tests and examinations associated with treating a patient suffering from diabetes. Diabetes is not a neurological disease nor are the blood tests associated with diabetes used to ascertain "motor function of the patient...verbal communication ability of the patient...and cognitive abilities of the patient" as in the present claimed invention.

The applicant also respectfully disagrees with the assertion made in the Office Action that Hennessy discloses "a computer readily accessible by the patient disposed at a location at which said patient is present substantially on a daily basis" as in the present claimed invention. While Hennessy does disclose in Col 2, lines 8-67 "the data may then be downloaded and/or transferred to a computer," the computer is not a requirement. Additionally, in Col 5, lines 30-67, Hennessy disclose a central database and computer memory. However, Hennessy (with Correa) neither disclose nor suggest "a computer readily accessible to a patient...substantially on a daily basis," as in the present claimed invention.

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The applicant further respectfully disagrees with the assertion that Hennessy disclose “an interactive procedure with said patient to obtain information selected from the group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient” as in the present claimed invention. Rather, in Col 6, lines 30-67 to Col 7, line 26 Hennessy discloses what information is included in the patient record such as test data, which includes “the office date, practitioner, and office visit comments. Clinical information, i.e. weight, height, blood pressure, smoking status, blood glucose recordations, neuropathy, skin condition, eye exam, are stored.” Also, quality of life indicators, a quality plan, medication, therapies and treatments are also included in the patient record disclosed by Hennessy. Thus, the information acquired by Hennessy is general information about the physiology of the patient. This is unlike the present claimed invention which discloses an interactive procedure between a patient and a computer used “to obtain information selected from the group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient” as in the present claimed invention. In fact, the information acquired by Hennessey would not be “the acquired information” of the present invention due to the distinct difference in the information acquired. Specifically, the information in Hennessey is not “selected from the group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient” as in the present claimed invention. Furthermore, Hennessey is directed towards monitoring a physiological disease i.e. diabetes, which is not “a neurological disease” as in the present claimed invention.



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Correa disclose a method of detecting depression and its severity. Similarly to Hennessey, Correa neither disclose nor suggest "an expert system accessible by said computer able to receive said information and produce a quantified indicator from said information and making said quantified indicator available to said computer" as in the present claimed invention. Nor does Correa (with Hennessey) disclose "an output unit connected to said computer for providing said quantified indicator to the patient" as asserted in the Office Action and claimed in the present invention. Contrary to the assertions made in the Office Action, in Col 1, lines 4-67 to Col 2, line 67 and Col 3, lines 1-41, Correa actually disclose a method "for detecting the presence and severity of depression by means of measuring the subject's color perception, and changes in color perception." Correa repeatedly recite throughout the application that color directly correlates to a level of depression and Correa specifically requires color to be obtained as an indication of the level of depression of the patient. Correa (with Hennessy) neither disclose nor suggest providing information characterizing a verbal communication ability, motor function, or cognitive ability of a patient to "an expert system...able to receive said information and produce a quantified indicator from said information" that describes the state of the patient suffering from a neurological disease as in the present claimed invention.

It is also respectfully submitted that there is no reason or motivation to combine these two references as Hennessy et al. is directed towards monitoring a chronic disease through physiological indicators while Correa are concerned with measuring the severity of depression through color perception. The type of disease monitored and means for monitoring this disease in each of Hennessey and Correa are totally unrelated. Individual diseases each require unique and subjective methods of monitoring and treatment. Thus, there would be no reason or motivation to combine teachings on treating and monitoring

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two different and unrelated diseases to produce a method or system for treating and monitoring a third unrelated disease, a neurological disease as in the present claimed invention.

Additionally, even if there is some motivation to combine these two references, such a combination would produce a system that monitors chronic disease and depression through physiological indicators and color perception. This combination would still not disclose "a method for allowing a patient, suffering from a neurological disease and receiving medication for said disease to self-monitor the patient's actual state" as in the present claimed invention. Nor would such a combination disclose "providing a computer at a location readily accessible to a patient substantially on a daily basis" as in the present claimed invention. This combination would also not disclose "conducting an interactive procedure between said patient and said computer to acquire information in said computer from the group consisting of **information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient**" as in the present claimed invention. Nor would the combination disclose both "making an expert system accessible by said computer and supplying said information from said computer to said expert system and, in said expert system, determining at least one quantified indicator describing the state of the patient suffering from a neurological disease, which is treated by medication;" and "providing said computer with an output device and making said quantified indicator available to the patient via said output device" as in the present claimed invention. Consequently, it is respectfully requested that the rejection of claims 19, 21, 27 and 28 be withdrawn.

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CLAIM 22

Claim 22 is dependent on Independent claim 17 and is considered patentable for the reasons presented above with respect to claim 17. Claim 22 is also considered patentable because Correa (with Hennessy and/or Saltzstein) provide no 35 USC 112 compliant enabling disclosure that makes the present invention as claimed in claim 22 unpatentable. Specifically, as acknowledged by the Examiner, Correa and Hennessy neither disclose nor suggests "acquiring information via an interactive procedure" as in the present claimed invention. Additionally, as discussed above with respect to claim 17, Correa and Hennessy neither discloses nor suggests that "the information is selected from a group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient" as in the present claimed invention.

Additionally, the Examiner cites column 3, lines 1 – 41 of Correa as disclosing the claimed feature. Applicant respectfully disagrees. Rather, in the section cited by the Examiner, Correa discloses the structure of a computer that is used to evaluate pre-determined questions for selectively determining a level of depression being suffered by a patient. As discussed above with respect to claims 1 and 17, Correa is specifically intended to focus on a single disease and uses information wholly unlike the information used to "self-monitor" a patient's neurological disease as in the present claimed invention. Specifically, Correa neither discloses nor suggests "said software...produces a quantified information value from said information" wherein the information is "selected from the group consisting of information characterizing a motor function of the patient, information characterizing verbal communication of abilities of the patient, and information characterizing cognitive abilities of the patient" as in the present claimed invention. The system disclosed by Correa is not "interactive" as in the present claimed invention and is

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concerned with information wholly unrelated to the “acquired information” of the present claimed invention. Consequently, it is respectfully requested that the rejection of claim 8 be withdrawn.

#### CLAIMS 23 – 26

Claim 23 is dependent on Independent claim 22 and is considered patentable for the reasons presented above with respect to claims 17 and 22. Claim 23 is also considered patentable because Hennessy (with Correa) provide no 35 USC 112 compliant enabling disclosure that makes the present invention as claimed in claim 23 unpatentable. Specifically, as acknowledged by the Examiner, Hennessy neither discloses nor suggests “acquiring information via an interactive procedure” as in the present claimed invention. Additionally, as discussed above with respect to claims 1 and 17, Hennessy neither discloses nor suggests that “the acquired information is selected from a group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient” as in the present claimed invention.

Applicant respectfully submits that the Examiner fundamentally misinterprets and misunderstands the system as disclosed by Hennessy. Column 7, lines 1 – 51 are cited as disclosing the present invention as claimed in claim 23. Applicant respectfully disagrees. Rather, Hennessy merely discloses the generation of a quality plan for treatment of a patient population having diabetes. The patient record of Hennessy includes the quality plan that is generated from a selected treatment guideline. All of the information that makes up each of the patient record and the guideline are input by a user and NOT “at least one software program...able to execute an interactive procedure with said patient to obtain information” from the patient as in the present claimed invention. Further, Hennessy neither discloses

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nor suggests a system that "produces an evaluation from said stored information with regard to a dosage of said medication" as in the present claimed invention. Moreover, the information used by Hennessy to generate the quality plan and guideline is wholly unlike the "obtained information" of the present claimed invention which "is selected from a group consisting of information characterizing motor function of the patient, information characterizing verbal communication ability of the patient, and information characterizing cognitive abilities of the patient". Consequently, it is respectfully submitted that the rejection of claim 23 be withdrawn.

Claims 24 – 26 are dependent on claim 23 and are considered patentable for the reasons discussed above with respect to claims 17, 22 and 23. Therefore, the arguments presented above with respect to claims 17, 22 and 23 are applicable to claims 24 – 26. Consequently, it is respectfully submitted that the rejection of claims 24 – 26 be withdrawn.

In view of the remarks presented above with respect to claim 17, it is respectfully submitted that Hennessy et al. and Correa et al., when taken alone or in combination provide no 35 USC 112 compliant enabling disclosure showing the features claimed in claim 17. As claims 19, 21 – 24 and 26 – 28 are dependent on claim 17, it is respectfully submitted that claims 19, 21 – 24 and 26 – 28 are patentable for the same reasons as claim 17 discussed above. It is thus further respectfully submitted that this rejection is satisfied and should be withdrawn.

### **VIII CONCLUSION**

Applicant respectfully submits that Hennessy, Correa and Saltzstein, alone or in combination, provides no 35 USC 112 compliant enabling disclosure that makes the present invention as claimed in claims 1 and 17 unpatentable. Specifically, Hennessy,

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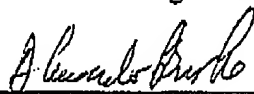
Correa and Saltzstein neither disclose nor suggest a method or system for "allowing a patient suffering from a neurological disease and receiving medication for treating said disease, to self-monitor a state of the patient" as in the present claimed invention. Additionally, Hennessy, Correa and Saltzstein neither disclose nor suggest executing "an interactive procedure with said patient to obtain (acquire) information" wherein "said information is selected from a group consisting of information characterizing a motor function of the patient, information characterizing verbal communication abilities of the patient, and information characterizing cognitive abilities of the patient" as in the present claimed invention. Furthermore, Hennessy, Correa and Saltzstein neither disclose nor suggest "providing said acquired patient information to said expert system, for processing thereby, and determining from the acquired information, at least one quantified indicator describing the state of the patient" as in the present claimed invention.

Accordingly it is respectfully submitted that the rejection of Claims 1-28 should be reversed.

Respectfully submitted,  
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**APPENDIX I - APPEALED CLAIMS**

1. (Previously Presented) A method for allowing a patient, suffering from a neurological disease and receiving medication for said disease, to self-monitor the patient's actual state, comprising the steps of:

providing a computer at a location readily accessible to a patient substantially on a daily basis for acquiring information from a patient;

acquiring information, via an interactive procedure, from a patient wherein the acquired information is selected from a group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient;

providing an expert system accessible by the computer;

providing said acquired patient information to said expert system for processing thereby, and determining, from the acquired information, at least one quantified indicator describing the state of the patient suffering from a neurological disease which is treated with medication; and

providing said computer with an output device and making said quantified indicator available to the patient via said output device.

2. (Previously Presented) A method as claimed in claim 1 wherein said information comprises information characterizing a motor function of said patient, and wherein the step of acquiring information comprises conducting software-controlled motor function exercises for quantifying at least one of neutral, negative and positive effects of said medication on said patient's state, and quantifying said negative and positive effects for processing by said expert system for use in determining said quantified indicator.

3. (Previously Presented) A method as claimed in claim 1 wherein said information is information characterizing a verbal communication ability of said patient, and wherein the step of acquiring information comprises acoustically acquiring speech from said patient and assessing said speech with a speech assessment system having speech recognition algorithms and a phonetic data bank to obtain an information value quantifying at least one of neutral, negative and positive effects of said medication on said speech, and supplying said information value to said expert

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system for processing by said expert system for use in determining said quantified indicator.

4. (Previously Presented) A method as claimed in claim 1 wherein said information is information characterizing cognitive abilities of the patient, and wherein the step of acquiring information comprises generating questions requiring a response from said patient to the respective questions and, from said responses, generating an information value quantifying at least one of neutral, negative and positive effects of said medication on said cognitive abilities of the patient, and supplying said information value to said expert system for processing for use in determining said quantified indicator.

5. (Previously Presented) A method as claimed in claim 4 comprising the step of acoustically entering said responses from said patient into said computer.

6. (Previously Presented) A method as claimed in claim 4 comprising the step of manually entering said responses from said patient into said computer.

7. (Previously Presented) A method as claimed in claim 1 comprising the step of entering additional information characterizing a subjective state of health of said patient during said step of acquiring information.

8. (Previously Presented) A method as claimed in claim 1 further comprising the step of obtaining a quantified information value representing said information acquired in said, step of acquiring and storing, after each interactive procedure, as stored information with respect to time, at least one of said quantified indicator, said acquired information and said quantified information value.

9. (Previously Presented) A method as claimed in claim 8 comprising providing said stored information to said expert system for producing an evaluation regarding dosage of said medication based on said stored information and making said evaluation available to the patient at said output device.



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10. (Previously Presented) A method as claimed in claim 9 wherein said stored information includes said quantified indicator, and wherein said expert system produces said evaluation from a chronological analysis of a curve relative to time of the respective quantified indicators obtained after each interactive procedure.

11. (Previously Presented) A method as claimed in claim 9 further comprising the step of making the chronological curve available to said patient as a displayed curve at said output device.

12. (Previously Presented) A method as claimed in claim 9 further comprising the step of storing said produced evaluation in a memory accessible by said computer.

13. (Previously Presented) A method as claimed in claim 10 further comprising the step of establishing communication between said computer and a physician located remote from said computer, and informing said physician of at least one of said quantified indicator, ~~and~~ said evaluation and said information, as transmitted information.

14. (Previously Presented) A method as claimed in claim 13 further comprising the step of transmitting therapy instructions from said physician to said computer based on an examination of said transmitted information, and making said therapy instructions available to the patient at said output device.

15. (Previously Presented) A method as claimed in claim 1 wherein said step of determining further comprises formulating said quantified indicator as a number.

16. (Previously Presented) A method as claimed in claim 1 wherein said step of determining further comprises formulating said quantified indicator as a statement.

17. (Previously Presented) A system for allowing a patient suffering from a neurological disease and receiving medication for treating said disease, to self-monitor a state of the patient, comprising:

a computer readily accessible by the patient disposed at a location at which said patient is present substantially on a daily basis;

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at least one software program installed in said computer able to execute an interactive procedure with said patient to obtain information selected from the group consisting of information characterizing a motor function of the patient, information characterizing verbal communication abilities of the patient, and information characterizing cognitive abilities of the patient;

an input unit connected to said computer for use by said patient during said interactive procedure for acquiring said information;

an expert system accessible by said computer able to receive said information and produce a quantified indicator from said information and making said quantified indicator available to said computer; and

an output unit connected to said computer for providing said quantified indicator to the patient.

18. (Previously Presented) A system as claimed in claim 17 wherein said information is information characterizing a motor function of the patient, and wherein said input unit is a manually operated input unit, and wherein said software program operates said computer to execute motor function test exercises and produces a quantified information value quantifying at least one of neutral, negative and positive effects of said medication on said motor function and makes said quantified information value available to said expert system.

19. (Original) A system as claimed in claim 17 wherein said information is information characterizing verbal communication abilities of the patient, and wherein said input unit is an acoustical input unit, and wherein said software program assesses speech made by said patient into said input unit using speech algorithms and a phonetic data bank, and produces a quantified information value representing said verbal communication abilities, and makes said quantified information value available to said expert system.

20. (Previously Presented) A system as claimed in claim 17 wherein said information is information characterizing cognitive abilities of the patient and wherein said software operates said computer to present questions to said patient and to receive responses from said patient, and produces a quantified information value from said responses quantifying at least one of neutral, negative and positive effects of said

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medication on said cognitive abilities, and makes said quantified information value available to said expert system.

21. (Original) A system as claimed in claim 17 comprising a further software program for operating said computer to obtain additional information from said patient characterizing a subjective state of health of said patient.

22. (Original) A system as claimed in claim 17 wherein said software program in each interactive procedure produces a quantified information value from said information, and further comprising a memory accessible by said computer and by said expert system for storing, as stored information relative to time, at least one of said quantified indicator, said information and said quantified information value after each interactive procedure.

23. (Original) A system as claimed in claim 22 wherein said expert system produces an evaluation from said stored information with regard to a dosage of said medication.

24. (Original) A system as claimed in claim 23 wherein said stored information includes said quantified indicator, and wherein said expert system produces said evaluation by analyzing a chronological curve of respective quantified indicators obtained from successive interactive procedures.

25. (Previously Presented) A system as claimed in claim 24 wherein said computer provides said chronological curve to said output device as a displayed curve.

26. (Original) A system as claimed in claim 23 further comprising a transmission link from said computer to an external computer located remotely from said computer for transmitting at least one of said evaluation and said quantified indicator to said external computer.

27. (Original) A system as claimed in claim 17 wherein said software operates said computer to formulate said quantified indicator as a number.

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28. (Original) A system as claimed in claim 17 wherein said software operates said computer to formulate said quantified indicator as a statement.

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**APPENDIX II - EVIDENCE**

Applicants rely on no evidence other than the arguments presented hereinabove.

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**APPENDIX III - RELATED PROCEEDINGS**

Applicants respectfully submit that there are no related proceedings in this present application.

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**APPENDIX IV - TABLE OF CASES**

1. *In re Fine*, 5 USPQ 2d 1600, (Fed Cir. 1988)
2. *ACS Hospital Systems Inc v. Montefiore Hospital*, 221 USPQ 929,933  
(Fed. Cir. 1984)
3. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (CCPA 1966)
4. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438  
(Fed.Cir. 1988), *cert. denied*, 488 U.S. 825 (1988)
5. *Ashland Oil Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 28, 293, 227 USPQ  
657, 664 (Fed.Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986)
6. *In re Oetiker*, 977 F2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992)

**APPENDIX V - LIST OF REFERENCES**

<u>U.S. Pat. No.</u>	<u>Issued Date</u>	<u>102(c) Date</u>	<u>Inventors</u>
6,277,071	March 16, 1999		Hennessy et al.
5,882,203	August 21, 2001		Correa et al.
5,941,829	August 24, 1999		Saltzstein et al.

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